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Application Number:NDA 20375/S008

APPROVAL LETTER

FEB 27 1998

Berlex Laboratories, Inc.
Attention: Ms. June K. Bray
Director
Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Bray:

Please refer to your supplemental new drug application dated August 28, 1997, received August 29, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara® (estradiol transdermal system).

The User Fee goal date for this application is February 28, 1998.

The supplemental application provides for a change in the appearance specification.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Diane Moore, Project Manager, at (301) 827-4260.

Sincerely,

/S/ 2/27/98

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry II
@ Division of Reproductive and Urologic Drug
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Original NDA 20-375
HFD-580/Div. Files
HFD-580/CSO/D.Moore
HFD-580/LRarick/Deputy/AMitra/MRhee
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: dm/February 26, 1998/n20375S008.doc

/S/

2/27/98

Concurrence:

TRumble, AMitra, MRhee 02.26.98

APPROVAL (AP)